

Express Mail No.: EL501 638 756US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Maroun, L.

Application No.: To Be Assigned  
(CON of application Serial No. 09/067,398)

Group Art Unit: To Be Assigned

Filed: Concurrently Herewith

Examiner: To Be Assigned

For: METHODS OF TREATMENT OF  
NEUROLOGICAL DISEASES BY  
INTERFERON ANTAGONISTS

Attorney Docket No.: 8221-006

**PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.115**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

In accordance with Rule 115 of the Rules of Practice, please enter the following amendments and consider the following remarks. Applicant submits herewith: (1) Exhibit A, a marked up version of the paragraph in the specification amended herein; (2) Exhibit B, a copy of the pending claims; (3) a Transmittal for filing a continuation application; (4) an Information Disclosure Statement; and (5) a revised PTO-1449 form.

**IN THE SPECIFICATION:**

Please amend the specification as follows:

On page 1, amend the paragraph beginning on line 4 to recite as follows:

This is a continuation of U.S. application Serial No. 09/067,398, filed April 28, 1998, which is a continuation of U.S. application Serial No. 08/502,519, filed July 14, 1995, now U.S. Patent No. 5,780,027, the contents of each of which is incorporated herein by reference in its entirety.

**IN THE CLAIMS:**

Please amend the claims, as follows:

Cancel Claims 1-17, without prejudice.

Add Claims 18-37, as follows:

18. (new) A method of treating dementia comprising administering to a human subject in need thereof an effective amount of an interferon antagonist.

19. (new) A method of treating dementia comprising administering to a human subject in need thereof an amount of an interferon antagonist that is effective in reducing the level of bioavailable interferon in a blood sample from the subject to at most one third of a normal level of bioavailable interferon in a human blood sample.

20. (new) A method of treating Alzheimer's disease comprising administering to a human subject in need thereof an effective amount of an interferon antagonist.

21. (new) A method of treating Alzheimer's disease comprising administering to a human subject in need thereof an amount of an interferon antagonist that is effective in reducing the level of bioavailable interferon in a blood sample from the subject to at most one third of a normal level of bioavailable interferon in a human blood sample.

22. (new) The method of claim 18, wherein the dementia is a type of dementia that is associated with an accumulation of amyloid in the central nervous system of the subject.

23. (new) The method of claim 19, wherein the dementia is a type of dementia that is associated with an accumulation of amyloid in the central nervous system of the subject.

24. (new) The method of Claim 19, wherein the interferon antagonist is a soluble interferon receptor, an interferon receptor fragment, or a peptide having an amino acid sequence that is derived from an interferon that occupies the receptor binding site but does not activate the receptor.

25. (new) The method of Claim 21, wherein the interferon antagonist is a soluble interferon receptor, an interferon receptor fragment, or a peptide having an amino acid

sequence that is derived from an interferon that occupies the receptor binding site but does not activate the receptor.

26. (new) The method of claim 19, wherein the interferon antagonist is an antibody.

27. (new) The method of claim 21, wherein the interferon antagonist is an antibody.

28. (new) The method of claim 19, wherein the interferon antagonist is a protein comprising an interferon-binding portion of an interferon receptor.

29. (new) The method of claim 21, wherein the interferon antagonist is a protein comprising an interferon-binding portion of an interferon receptor.

30. (new) The method of claim 19, wherein the antagonist blocks production of interferon.

31. (new) The method of claim 21, wherein the antagonist blocks production of interferon.

32. (new) The method of Claim 26, wherein the amount of antibody administered is between 1 and 100 mg/kg.

33. (new) The method of Claim 27, wherein the amount of antibody administered is between 1 and 100 mg/kg.

34. (new) The method of Claim 26, wherein the antibody is administered intramuscularly, subcutaneously or intravenously.

35. (new) The method of Claim 27, wherein the antibody is administered intramuscularly, subcutaneously or intravenously.

36. (new) The method of claim 20, wherein the human subject has Down's syndrome.

37. (new) The method of claim 21, wherein the human subject has Down's syndrome.

#### REMARKS

Claims 1-17 were pending in this application. Claims 1-17 have been canceled, without prejudice to Applicant's right to pursue the subject matter of the canceled claims in future applications. New Claims 18-37 have been added to more particularly point out and distinctly claim the subject matter of the invention. Claims 18-37 are, therefore, pending in the instant application. The new claims are fully supported by the instant specification, *e.g.*, see page 1, lines 7-11 and page 8, line 1 to page 12, line 2, and do not constitute new matter. A courtesy copy of the pending claims is included herewith as Exhibit B.

The specification has been amended to correct the claim to priority recited in the specification as originally filed. Specifically, the specification has been amended to indicate that the instant application is a continuation of U.S. application Serial No. 09/067,398, filed April 28, 1998, which is a continuation of U.S. application Serial No. 08/502,519, filed July 14, 1995, now U.S. Patent No. 5,780,027. A marked up version of the paragraph in the specification which has been amended, with the deletions and additions to the paragraph indicated by bracketing and underlining, respectively, is attached hereto as Exhibit A. The amendments to the specification do not constitute new matter.

Applicant respectfully requests entry and consideration of the foregoing amendments and remarks.

Respectfully submitted,

Date: April 30, 2001

Brian M. Poissant 28,462  
Brian M. Poissant (Reg. No.)

By: Anthony M. Insogna 35,203  
Anthony M. Insogna (Reg. No.)

**PENNIE & EDMONDS LLP**  
1155 Avenue of the Americas  
New York, N.Y. 10036-2711  
(212) 790-9090

Enclosure

**EXHIBIT A**  
**MARKED UP VERSION OF THE PARAGRAPH**  
**IN THE SPECIFICATION AMENDED IN**  
**THE PRELIMINARY AMENDMENT FILED APRIL 30, 2001**  
**ATTORNEY DOCKET NO. 8221-006**

---

On page 1, amend the paragraph beginning on line 4 as follows:

This is a continuation of U.S. application Serial No. [08/502,519, filed July 14, 1995] 09/067,398, filed April 28, 1998, which is a continuation of U.S. application Serial No. 08/502,519, filed July 14, 1995, now U.S. Patent No. 5,780,027, the contents of each of which is incorporated herein by reference in its entirety.

**EXHIBIT B**  
**PENDING CLAIMS**  
**UPON ENTRY OF THE PRELIMINARY AMENDMENT**  
**(filed April 30, 2001 under 37 C.F.R. § 1.115)**

**ATTORNEY DOCKET NO. 8221-006**

---

18. A method of treating dementia comprising administering to a human subject in need thereof an effective amount of an interferon antagonist.

19. A method of treating dementia comprising administering to a human subject in need thereof an amount of an interferon antagonist that is effective in reducing the level of bioavailable interferon in a blood sample from the subject to at most one third of a normal level of bioavailable interferon in a human blood sample.

20. A method of treating Alzheimer's disease comprising administering to a human subject in need thereof an effective amount of an interferon antagonist.

21. A method of treating Alzheimer's disease comprising administering to a human subject in need thereof an amount of an interferon antagonist that is effective in reducing the level of bioavailable interferon in a blood sample from the subject to at most one third of a normal level of bioavailable interferon in a human blood sample.

22. The method of Claim 18, wherein the dementia is a type of dementia that is associated with an accumulation of amyloid in the central nervous system of the subject.

23. The method of Claim 19, wherein the dementia is a type of dementia that is associated with an accumulation of amyloid in the central nervous system of the subject.

24. The method of Claim 19, wherein the interferon antagonist is a soluble interferon receptor, an interferon receptor fragment, or a peptide having an amino acid sequence that is derived from an interferon that occupies the receptor binding site but does not activate the receptor.

25. The method of Claim 21, wherein the interferon antagonist is a soluble interferon receptor, an interferon receptor fragment, or a peptide having an amino acid

sequence that is derived from an interferon that occupies the receptor binding site but does not activate the receptor.

26. The method of Claim 19, wherein the interferon antagonist is an antibody.
27. The method of Claim 21, wherein the interferon antagonist is an antibody.
28. The method of Claim 19, wherein the interferon antagonist is a protein comprising an interferon-binding portion of an interferon receptor.
29. The method of Claim 21, wherein the interferon antagonist is a protein comprising an interferon-binding portion of an interferon receptor.
30. The method of Claim 19, wherein the antagonist blocks production of interferon.
31. The method of Claim 21, wherein the antagonist blocks production of interferon.
32. The method of Claim 26, wherein the amount of antibody administered is between 1 and 100 mg/kg.
33. The method of Claim 27, wherein the amount of antibody administered is between 1 and 100 mg/kg.
34. The method of Claim 26, wherein the antibody is administered intramuscularly, subcutaneously or intravenously.
35. The method of Claim 27, wherein the antibody is administered intramuscularly, subcutaneously or intravenously.
36. The method of Claim 20, wherein the human subject has Down's syndrome.
37. The method of Claim 21, wherein the human subject has Down's syndrome.